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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,488	08/25/2003	Kai-yu Tong	MCHK/131/US	2363
2543 7590 04/01/2009 ALIX YALE & RISTAS LLP 750 MAIN STREET SUITE 1400 HARTFORD, CT 06103			EXAMINER BOCKELMAN, MARK	
			ART UNIT	PAPER NUMBER
			3766	
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			04/01/2009 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/647,488

Applicant(s)

TONG, KAI-YU

Examiner

Mark W. Bockelman

Art Unit

3766

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-5-2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-9 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner finds no support for what is now being claimed in applicant's original disclosure. Applicant briefly mentions figure 4 for support, however, contrary to what applicant's discussion in his arguments, all figure 4 shows is an intensity versus time stimulation graph. There are no indications on the graph of any timing events whatsoever and moreover no discussion of first and second control signals being associated with a heel switch activation. Not even the

initial activation during the heel lift is discussed with respect to this figure. However, from applicant's specification and the prior art it would appear that the heel lift switch signal initiates the entire stimulation sequence of rise, stimulation, extension and fall. Applicant now claims that that stimulation sequence has two portions activated by heel lift and foot placement. Such an assertion does not even make sense with what the device is trying to accomplish. The stimulation provided by applicant's device is to cause muscle contraction to enabling walking by lifting the foot. The switch in the heel appears to be activated by raising the heel to open the switch which contracts the muscle to "raise the foot during step" - page 6 , line 21 of applicants specification. The stimulation for contraction is shown to be at a continuous amplitude until the fall portion is reached. From applicant's disclosure, the switch cannot provide a "second signal" until the heel puts pressure on the switch as the foot is placed. The "second signal" would be, at best guess from the prior art given no specific disclosure by applicant), an "off" signal and no stimulation to the electrode would be applied. If the sequence of events that applicant now claims were to happen, the user would have a very difficult time walking since the foot is raised by a continuous stimulation (extension portion) that is designed to lift the foot when it is trying to be placed. Effectively the person would be walking on his heels. One of ordinary skill in the art would probably guess the fall portion disclosed by applicant to be designed to allow foot placement, especially when reading prior art literature such as Haughland. Haughland mentions varying the intensity of the stimulation through the swing portion to decrease it during part of the swing phase at paragraph [0091]. Thus, not only does applicant fail to provide any clear support for

what is being claimed, the claim does not make sense and seems to conflict with applicant's original disclosure in what they are trying to accomplish. In addition, there is no corresponding disclosure for the "files" being used in claim 11 in conjunction with the first and second control signals and certainly no second control signal being applied to the electrode during foot placement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 11 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Haugland et al. USPN 2003/0144710. Haugland et al. teaches the invention as claimed as established in previous office actions. Applicant now recites that that the device uses a second control signal output to the electrode upon foot placement. Haugland in paragraphs [0090]-[0091] teaches that a rise portion and an stimulation portion is applied during heel lift and at least the beginning of the swing gait. He also teaches that a brief stimulation is applied upon heel impact for balance. Such a brief stimulation inherently can be considered as an extension period to the end of the gait period and would inherently have a fall portion as it turned off no matter how abrupt. While applicant argues that

Haugland teaches that the gait portion falls to zero (without citation) such would not preclude the brief stimulation period to be an extension. The input to the controller is set by the user but programs set up the stimulation pattern [0092], which the examiner considers to be files. If not inherent, any alleged differences would be obvious since well known techniques would be easily be applied to accomplish the described outcome by Haugland.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1, 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland et al., US 2003/0144710 in view of Nelson et al., USPN 5586557.

Haugland teaches a heel switch placed under the heel of a user for generating a stimulation signal when the foot is lifted during gait (Fig. 5, para. 60), an electrode adapted to contact the user's leg (Fig. 5, paras. 60-65), and a controller coupled to the heel switch and electrode for outputting a stimulation signal to the electrode (Fig. 5, paras. 78-80). Applicant's original disclosure fails to explain the significance and differences between the four portions of the stimulation signal (i.e. rise, stimulation, extension, and fall portions) other than merely being depicted in Fig. 4. Haugland is

interpreted as disclosing a stimulation signal having a rise portion, a stimulation portion, an extension portion and a fall portion (paras. [0090]-[0091] as well as a second application of stimulation increase for a brief period after the heel contacts the floor to help balance the person (last line of paragraph [0091]). It is inherent or obvious that heel switch signals for the application of such second stimulation Nelson also teaches a device for evaluating the gait of an individual using a heel switch and calculating a duration of use and a number of steps taken over that duration (column 3, lines 15-17) to determine an ambulation index. Since Nelson is directed to a device for analyzing and monitoring ambulation during rehabilitation (column 1, lines 11-15), it would have been obvious to incorporate recording the number of steps taken during gait as taught in Nelson into the device of Haugland to more effectively monitor a patient's recovery status during rehabilitation.

Claims 2 and 4-6, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland in view of Nelson as applied to claim 1 above, and further in view of Smith et al., USPN 5485402.

As discussed above, Haugland teaches a heel switch placed under the heel of a user for generating a stimulation signal when the foot is lifted during gait (Fig. 5, para. 60), an electrode adapted to contact the user's leg (Fig. 5, paras. 60-65), and a controller coupled to the heel switch and electrode for outputting a stimulation signal to the electrode (Fig. 5, paras. 78-80). The controller is contained in a housing which also includes a receiver for receiving wireless signals from a remote unit (paras. 80, 85), and

stores stimulation data (para. 80). The remote unit may be a hand-held computer that is removably coupled to the controller (para. 85). Again, Haugland is interpreted as disclosing a stimulation signal having a rise portion, a stimulation portion, an extension portion and a fall portion (paras. 90-91). Similarly, Applicant's specification fails to discuss the stimulation data as including a stimulation level, a rise time, a stimulation time, a stimulation time, an extension time, a fall time, a pulse form, a triggering period, a triggering method and a triggering criteria. To the extent that these features are understood, they are considered to be inherently present in Haugland (paras. 73, 79-80, 85-92, 95, 114, 129-133).

While Nelson teaches measuring a duration of use and number of steps taken during that duration, Nelson does not teach recording the number of steps taken in a predetermined duration such as an hour, a day, or a period of dates. Smith on the other hand, discloses storing a number of steps taken during a selected time interval, including hourly or daily (column 4, line 52 - column 5, line 25, Figs. 4-5). Like Nelson, Smith is also directed to a gait activity monitor which may be used for patient rehabilitation. Therefore, it would have been obvious to one of ordinary skill in the art to specify a time interval and count and store the number of steps taken during that interval as taught by Smith, while rehabilitating a patient using the device taught by Haugland modified by Nelson, to provide a more effective means of monitoring a patient's progress during rehabilitation.

Claims 7-8 rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland in view of Nelson and Smith as applied to claims 2, 4-6 and 9 above, and further in view of Sieracki et al, US 2004/0143302.

Haugland, Nelson and Smith disclose each feature of the claimed invention, as discussed above, except for the limitation that the computer may be a Personal Digital Assistant and uses Windows as the graphic user interface. Both of these features are well known. For example, there are several well known types of computers, including desktops, laptops, and PDAs. Moreover, many of these types of computers and other electronic devices (eg cell phones) also use Windows. Sieracki is one example of a programmable therapeutic stimulating device which uses a PDA as the external controller (Fig. 1). It would have been obvious to one of ordinary skill in the art to use a PDA as the computer and/or to use Windows in the computer of Haugland as these are standard options for any application requiring a computer.

Response to Arguments

Applicant's arguments filed 1-5-2009 have been fully considered but they are not persuasive. Applicant introduces new claim language that has no support in the disclosure as originally filed and is considered new matter. The applicant merely refers to his figure 4 and then alleges that that recited sequence now claimed is shown. For applicant to be fully responsive to the next amendment, the examiner requires applicant to show in detail how they surmised this detailed explanation from the figure shown, the examiner does not find any of the alleged teachings therein. The Haugland device

indicates the use of a second control signal after heel impact to help control stability. Unlike applicant's specification, the Haughland et al. disclosure teaches or suggests applicant's invention as now claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272 -4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark W Bockelman/
Primary Examiner, Art Unit 3766
March 29, 2009